



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,957	10/19/2005	Vijay C Chhabada	053229	9977

38834 7590 05/01/2008
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER

SHAMEEM, GOLAM M

ART UNIT	PAPER NUMBER
----------	--------------

1626

MAIL DATE	DELIVERY MODE
-----------	---------------

05/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,957	Applicant(s) CHHABADA ET AL.	
	Examiner Golam M. M. Shameem, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/06;10/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application is a 371 of PCT/IN04/00052 03/04/2004 is acknowledged.

Status of Claims

Claims 1-6, 9, 11 and 12 are currently pending in the application. Claims 7-8 and 10 have been canceled.

Receipt is acknowledged of amendment / response filed on March 10, 2008 and that has been entered.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 08/28/2006, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, (which includes claims 1-6 drawn to a process for preparation of a compound of the formula I) **without traverse** is acknowledged. However, in view of a fair interpretation of the claims, the Examiner will rejoin remaining claims 9, 11 and 12 of Group II to the elected Group I (because they fall within the scope of elected invention), and therefore, the requirement for restriction is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

Art Unit: 1626

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9, 11 and 12 are rejected under 35 U.S.C. § 103(a) as being anticipated by Ratkai *et al* (1999, EP 918055 A1) and further in view of Kankan *et al* (1999, IN 186587).

Applicant claims a process for preparation of 1-[9H-carbazol-4-yloxy]-3-[2-2-(methoxy)phenoxy-ethyl-amino]-propan-2-ol.

Determination of the scope and content of the prior art (MPEP §2141.01)

Ratkai *et al* teach the process for preparation of 1-[9H-carbazol-4-yloxy]-3-[2-2-(methoxy)phenoxy-ethyl-amino]-propan-2-ol compounds (claims 1-4, pages 13-15) similar to those of instantly claimed invention. Kankan *et al* also teach an improved process (pages 1-5) for the manufacture of carvedilol.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the process taught in the references and the claimed process herein lies merely in the variation of reagents and reaction conditions such as organic solvent, catalyst combination ranges etc. The differences between the instant claims and the prior art references are so negligible, that one of ordinary skill in the chemical arts would expect slight variations to be within the expected purview of 35 U.S.C. 103(a). The disclosure of Ratkai *et al* and Kankan *et al* teach several combinations that would easily place Applicants invention in possession of the public at the time of Applicants invention was filed.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

It is obvious to prepare compounds by an old method using analogous starting materials (such as, reacting Formula 2 with Formula 5 to obtain Formula 6) and determining optimum reaction conditions in the absence of any unobvious or unexpected results. The motivation to make the claimed process derives from the expectation that the use of analogous reagents and reaction conditions including use of organic solvent such as ethyl acetate, debenzylation reaction by catalytic hydrogenation using palladium on carbon (see Ratkai *et al* , page 14-15, claims 1 and 2, and also, Kankan *et al* page 5, lines 8 and 13-14) under specific set of reaction conditions would have made similar yield of products. The selection of reaction conditions is more optimization by more modification of routine experimentation and within one skilled in the art (In re Aller, *et al.*, 105 USPQ 233). Since there is an exemplary teaching in the prior art to obtain the instantly claimed process, it is obvious for those ordinary skilled in the chemical art with a reasonable expectation of success that such modification and optimization of reaction conditions would give process with similar rate of recovery. In the absence of objective evidence showing an unexpected result, the obviousness rejection is deemed to be proper.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem, Ph.D./
Primary Patent Examiner
Art Unit 1626
Technology Center 1600

Application/Control Number: 10/553,957
Art Unit: 1626

Page 6

Application/Control Number: 10/553,957
Art Unit: 1626

Page 7